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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,742	09/17/2003	Magnus Bolmsjo	211.313	4686

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EXAMINER	
MARCETICH, ADAM M	

ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,742	BOLMSJO ET AL.	
	Examiner	Art Unit	
	Adam Marcetich	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-91* is/are pending in the application.

4a) Of the above claim(s) *49-91* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :17 Sept 2003, 04 Feb 2004, 09 Feb 2004, 25 May 2005.

DETAILED ACTION

Election/Restrictions

1. Claims 49-87 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 18 September 2007. Claims 1-48 are being examined on the merits.

Information Disclosure Statement

2. The information disclosure statement filed 09 February 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. A copy of "WO9116005 International (PCT)" has not been received, and therefore the reference has not been considered.

Claim Objections

3. Claims 1 and 31 are objected to because of the following informalities:

4. Regarding claim 1, the language "extending between the distal end proximal ends" in line 17 should be changed to "extending between the distal and proximal ends" for clarity.

5. Regarding claim 31, the language "has a unit within the urinary tract to the use position" should be changed to "has a unit that can be placed within the urinary tract [[to the]] during the use position" or similar language for clarity.

6. Appropriate correction is required.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rioux et al. (US Patent 6,494,855) in view of Gellman (US Patent Application Publication No. 2004/0078088).

10. Regarding claims 1 and 42, Rioux discloses an indwelling catheter to drain urine from a bladder to a location adjacent to a urinary sphincter muscle in a urinary tract

which also includes a urinary canal extending from the sphincter muscle to an exterior opening, comprising:

a main body having a distal end, a proximal end and a length sufficient to position the distal end within the bladder and to position the proximal end adjacent to and distal of the sphincter muscle within the urinary tract, the main body defining an urine drainage interior passageway extending from the distal end to the proximal end (column 4, lines 52-57 and Fig. 3, first tubular segment 10);

a balloon attached to the distal end of the main body, the balloon expandable in size within the bladder to maintain the distal end in the bladder and restrain the main body against proximal movement within the urinary tract from a use position, the use position locating the distal end of the main body in the bladder and the proximal end of the main body adjacent to and distal of the sphincter muscle (column 7, lines 40-42 and Fig. 3, inflatable balloon 1); and

an inflation tube having a distal end, a proximal end and a length extending between the distal end proximal ends, the distal end connected to the main body, the length sufficient to extend from the main body through the urinary canal to the exterior opening when the main body is in the use position, the inflation tube and the main body defining an inflation passageway extending from the proximal end of the inflation tube to the balloon through which to deliver inflation fluid for expanding the balloon (column 7, lines 42-47 and Fig. 3, tube 3 connected to inflatable balloon 1).

Rioux discloses the invention as substantially claimed. See above. However, Rioux lacks a coiled or configuration section of an inflation tube as claimed [claims 1

and 42]. Gellman discloses a coiled section of a urethral stent capable of being placed within the urinary canal adjacent to and proximal of the sphincter muscle when the main body is located in a use position, the coiled section capable of interacting with a constriction of the urinary tract by the sphincter muscle to restrain the main body against distal movement within the urinary tract from a use position (paragraphs [0036], [0037] and Figs. 5A and 5B, bulbar segment 20 of prostatic stent 10).

Gellman provides the advantage of radial strength for a stent while conforming to a patient's anatomy (paragraph [0045]). Gellman also provides the advantage of anchoring a stent within a patient's urethra (paragraph [0042] and Figs. 5A and 5B). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Rioux with a coiled section as taught by Gellman in order to provide radial strength and anchoring for a urethral stent.

11. Regarding claims 2-4, 6 and 7, Rioux discloses the invention as substantially claimed. See above. However, Rioux lacks a coiled section as claimed [claims 2-4, 6 and 7]. Gellman discloses a coiled section of a urethral stent resilient in a transverse dimension and in a longitudinal dimension (paragraph [0038], "The windings 15 [are] ... sufficiently flexible to conform to the shape of the urethra"). Therefore it naturally follows that windings 15 of Gellman are each resilient in a transverse dimension and collectively resilient in a longitudinal dimension.

Gellman provides the advantage of radial strength for a stent while conforming to a patient's anatomy (paragraph [0045]). Gellman also provides the advantage of anchoring a stent within a patient's urethra (paragraph [0042] and Figs. 5A and 5B).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Rioux as discussed with the resilient coiled section of a urethral stent as taught by Gellman in order to provide radial strength and anchoring for a urethral stent.

Regarding the limitation of decreasing in a transverse dimension upon elongation in a longitudinal dimension, Examiner notes that this property is inherent to a coil shape. When a coil shape is elongated in a longitudinal dimension, it will decrease in a transverse dimension.

12. Regarding claim 5, Rioux discloses the invention as substantially claimed. See above. However, Rioux lacks a coiled section comprising a plurality of individual adjacent coils each formed by the inflation tube as claimed [claim 5]. Gellman discloses a coiled section comprising a plurality of individual adjacent coils (paragraphs [0036], [0037] and Fig. 1A, plurality of windings 15). Regarding rationale and motivation, see discussion of claims 1 and 42 above.

13. Regarding claims 8 and 9, Rioux discloses the invention as substantially claimed, including a main body having an outer transverse dimension. See above. However, Rioux lacks a coiled section as claimed [claims 8 and 9]. Gellman depicts a coiled section having:

an outer transverse dimension, the outer transverse dimension of the coiled section being greater than the outer transverse dimension of the main body (paragraph [0047] and Fig. 4A, bulbar segment 20 of Gellman capable of having dimension larger than first tubular segment 10 of Rioux); and

a center opening having an inner transverse dimension, and the inner transverse dimension of the coiled section is substantially the same as the exterior transverse dimension of the main body (paragraph [0047] and Fig. 4B, bulbar segment 20 of Gellman capable of having substantially the same outer dimension as first tubular segment 10 of Rioux). These size arrangements are adaptable to be used with the invention of Rioux as discussed. Regarding rationale and motivation, see discussion of claims 1 and 42 above.

14. Regarding claims 10, 11, 19, 30 and 40, Rioux discloses the invention as substantially claimed. See above. However, Rioux lacks an insertion tool as claimed [claims 10, 11, 19, 30 and 40]. Gellman discloses an indwelling catheter in combination with:

an insertion tool for connection to the indwelling catheter to move the indwelling catheter within the urinary tract to the use position, the insertion tool having first and second opposite ends and a length sufficient to position the first end within the urinary tract distal of the sphincter muscle while the second end is at the exterior of the urinary canal; and wherein the insertion tool extends through the center opening of the coiled section (paragraphs [0047] and [0052]; Figs. 4A and 4B, stationary element 54 of delivery system 40 fitting within second / bulbar segment 20);

an insertion tool having an exterior transverse dimension, and the exterior transverse dimension of the insertion tool is substantially the same as the exterior transverse dimension of the main body (paragraph [0048] and Fig. 4B, bulbar segment

20 having substantially same inner dimension as stationary element 54 of delivery system 40);

the insertion tool defines an interior channel extending between the first and second opposite ends of the insertion tool (paragraph [0047] and Fig. 3, stationary element 54 having lumen for rotatable element 42); and

the interior channel of the insertion tool is in fluid communication with the interior passageway of the main body when the insertion tool is connected to the indwelling catheter at the separable connection (Figs. 4A and 4B, stationary element 54 substantially in fluid connection with bulbar segment 20).

Gellman provides the advantage of delivering a stent within a prostatic urethra (paragraph [0052]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Rioux as discussed with the insertion tool as taught by Gellman in order to deliver a stent within a prostatic urethra.

15. Regarding claims 12, 13 and 22, Rioux discloses the invention as substantially claimed. See above. However, Rioux lacks a separable connection as claimed [claims 12 and 13]. Gellman discloses an indwelling catheter further comprising:

a separable connection between the main body and the insertion tool to permit disconnection of the indwelling catheter and the insertion tool upon locating the indwelling catheter in the use position (paragraph [0052]; Figs. 3, 4A and 4B, delivery system 40 capable of forming separable connection with stent 10);

wherein the separable connection retains the main body to the insertion tool to permit movement of the insertion tool and the indwelling catheter as a unit when positioning the indwelling catheter in the use position (paragraph [0052]; Figs. 3, 4A and 4B delivery system 40 capable of retaining stent 10 during positioning); and

the separable connection permits separation of the indwelling catheter and the insertion tool in response to continued proximal movement of the insertion tool when the expanded balloon restrains the main body against proximal movement from the use position (paragraph [0052]; Figs. 3, 4A and 4B, delivery system 40 capable of detaching in response to force pulling stent 10 away from end).

Regarding rationale and motivation, see discussion of claims 10, 11, 19, 30 and 40 above.

16. Regarding claims 14 and 25, Rioux discloses the invention as substantially claimed. See above. However, Rioux lacks a selectively disconnectable bridging structure as claimed [claims 14 and 25].

Gellman discloses a separable connection including a selectively disconnectable bridging structure extending between the main body and the insertion tool, the bridging structure fastening the main body to the insertion tool when connected, the bridging structure releasing the main body from the insertion tool when the bridging structure is disconnected to permit separation of the indwelling catheter from the insertion tool in response to continued proximal movement of the insertion tool when the expanded balloon restrains the main body against proximal movement from the use position

(paragraph [0047] and Fig. 3, delivery system 40 comprising connection arm 46 and opening 52 permitting connection to bulbar segment 20).

Gellman provides the advantage of securing a stent with an insertion tool during manipulation (paragraph [0047]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Rioux as discussed with the selectively disconnectable bridging structure as taught by Gellman in order to secure a stent with an insertion tool.

17. Regarding claims 15, 26 and 36, Rioux discloses a cord capable of extending between a main body and insertion tool (column 5, lines 55-63 and Fig. 3, retrieval piece 25). However, Rioux lacks an insertion tool as claimed [claims 15, 26 and 36]. Gellman discloses an insertion tool (paragraphs [0047] and [0052]; Figs. 4A and 4B, stationary element 54 of delivery system 40. Regarding rationale and motivation, see discussion of claims 10, 11, 19, 30 and 40 above.

Modifying the invention of Rioux with the insertion tool of Gellman allows:

a cord to extend between a main body and an insertion tool when the bridging structure connects the main body to the bridging tool; and

the extension of the cord between the main body and the insertion tool to be eliminated when the bridging structure is disconnected.

Examiner notes that the claims are drawn to a device, not a method of using.

18. Regarding claims 16-18, 27-29 and 37-39, Rioux discloses the invention as substantially claimed. See above. However, Rioux lacks an insertion tool as claimed [claims 16-18, 27-29 and 37-39]. Gellman discloses an insertion tool (paragraphs [0047]

and [0052]; Figs. 4A and 4B, stationary element 54 of delivery system 40. Regarding rationale and motivation, see discussion of claims 10, 11, 19, 30 and 40 above. Modifying the invention of Rioux with the insertion tool of Gellman provides an indwelling catheter wherein:

the insertion tool defines an interior channel extending between the first and second opposite ends of the insertion tool (paragraph [0047] and Fig. 3, stationary element 54 having lumen for rotatable element 42);

the interior channel of the insertion tool is in fluid communication with the interior passageway of the main body when the insertion tool is connected to the indwelling catheter at the separable connection (Figs. 4A and 4B, stationary element 54 substantially in fluid connection with bulbar segment 20); and

the cord is capable of extending from a separable connection through the interior channel to a second end of the insertion tool when the bridging structure connects the main body to the insertion tool (Fig. 3, retrieval piece 25 of Rioux capable of extending through lumen in stationary element 54 of Gellman). Gellman provides the advantage of securing an insertion tool to an indwelling catheter during insertion.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Rioux with the insertion tool lumen as taught by Gellman in order to secure an insertion tool to an indwelling catheter during insertion.

Examiner notes that the limitations of extending a cord through an interior channel are being interpreted as functional language and that the claims are drawn to a device, not a method of using.

19. Regarding claims 20, 21 and 43, Rioux discloses the invention as substantially claimed. See above. However, Rioux lacks an insertion tool as claimed [claims 20, 21 and 43]. Gellman discloses indwelling catheter in combination with:

an insertion tool for connection to the main body to move the indwelling catheter within the urinary tract to the use position, the insertion tool having first and second opposite ends and a length sufficient to position the first end within the urinary tract distal of the sphincter muscle while the second end is at the exterior of the urinary canal (paragraphs [0047] and [0052]; Figs. 4A and 4B, stationary element 54 of delivery system 40 fitting within second / bulbar segment 20);

a separable connection between the main body and the insertion tool (paragraph [0052]; Figs. 3, 4A and 4B delivery system 40 capable of retaining stent 10 during positioning); and wherein:

the coiled section winds around the insertion tool when the insertion tool is connected to the indwelling catheter (Figs. 4A and 4B, bulbar segment 20 substantially capable of winding around stationary segment 54).

Gellman provides the advantage of improving stent manipulation during insertion (paragraph [0047]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Rioux as discussed

with the insertion tool as taught by Gellman in order to improve stent manipulation during insertion.

20. Regarding claims 23, 24, 45 and 46, Rioux discloses the invention as substantially claimed. See above. However, Rioux lacks an insertion tool as claimed [23, 24, 45 and 46]. Gellman discloses an indwelling catheter wherein:

an insertion tool is removable from within a coiled section in response to a predetermined amount of proximal movement of the insertion tool in the urinary canal relative to the main body after separation at the separable connection (paragraph [0052], stationary element 54 removable from patient's urinary system after deployment of prostatic stent 10); and

a coiled section permits substantially unimpeded proximal movement of the insertion tool within the coiled section after separation at the separable connection (paragraph [0052], stationary element 54 removable from patient's urinary system in proximal direction after deployment of prostatic stent 10). Regarding rationale and motivation, see discussion of claims 10, 11, 19, 30 and 40 above.

21. Regarding claims 31 and 47, Rioux discloses the invention as substantially claimed. See above. However, Rioux lacks a coiled section as claimed [claims 31 and 47]. Gellman discloses an indwelling catheter wherein:

a coiled section maintains a portion of a stent between the coiled section and the proximal end of the main body substantially in alignment with a portion of the insertion tool during movement of the indwelling catheter and the insertion tool has a unit within

the urinary tract to the use position (Figs. 4A and 4B depicting stent 10 substantially in alignment with stationary element 54 of delivery system 40).

Gellman provides the advantage of providing support and alignment for a stent during implanting. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Rioux with a coiled section as taught by Gellman in order to provide support for a stent during implanting.

22. Regarding claims 32 and 48, Rioux discloses an indwelling catheter for use with a syringe having a nozzle, further comprising a valve assembly connected to the proximal end of the inflation tube, the valve assembly including a receptacle by which to connect the nozzle of the syringe for transferring inflation fluid from the syringe into the inflation passageway for inflating the balloon (column 7, lines 40-48 and Fig. 3, check valve 22 and inflation source 8 comprising a syringe). Since Fig. 3 depicts check valve 22 and inflation source 8 as connected, it naturally follows that a syringe has a nozzle, and check valve 22 comprises a receptacle by which to connect the nozzle of the syringe.

23. Regarding claims 33 and 44, Rioux discloses the invention as substantially claimed. See above. However, Rioux lacks an insertion tool as claimed [claims 33 and 44]. Gellman discloses an indwelling catheter wherein:

an insertion tool has an exterior surface (Figs. 4A and 4B depicting stationary element 54 of delivery system 40 having exterior surface); and

an inflation tube extends along the exterior surface of the insertion tool when the main body is connected to the insertion tool (Fig. 3 of Rioux depicting tube 3

substantially capable of extending along exterior surface of stationary element 54 of Gellman). Examiner notes that the limitation of positioning an inflation tube is being interpreted as functional language. Regarding rationale and motivation, see discussion of claims 10, 11, 19, 30 and 40 above.

24. Regarding claims 34 and 35, Rioux discloses an assembly of an indwelling catheter used to drain urine from a bladder to a location adjacent to a urinary sphincter muscle in a urinary tract which also includes a urinary canal extending from the sphincter muscle to an exterior opening, the assembly comprising:

a main body of the indwelling catheter, the catheter main body having a distal end, a proximal end and a length sufficient to position the distal end within the bladder and to position the proximal end adjacent to and distal of the sphincter muscle within the urinary tract, the catheter main body defining an urine drainage interior passageway extending from the distal end to the proximal end (column 4, lines 52-57 and Fig. 3, first tubular segment 10);

a balloon attached to the distal end of the catheter main body, the balloon expandable in size within the bladder (column 7, lines 40-42 and Fig. 3, inflatable balloon 1);

Rioux discloses the invention as substantially claimed. See above. However, Rioux lacks an insertion tool, separable connection between the catheter main body and the tool main body, and selectively disconnectable bridging structure as claimed [claims 34 and 35]. Gellman discloses:

a main body of an insertion tool, the tool main body first and second opposite ends and a length sufficient to position the first end within the urinary tract distal of the sphincter muscle while the second end is at the exterior of the urinary canal (paragraphs [0047] and [0052]; Figs. 4A and 4B, stationary element 54 of delivery system 40 fitting within second / bulbar segment 20);

a separable connection between the catheter main body and the tool main body, the separable connection maintaining the insertion tool connected to the indwelling catheter for movement as a unit when positioning the indwelling catheter in a use position, the use position locating the distal end of the catheter main body in the bladder and the proximal end of the catheter main body adjacent to and distal of the sphincter muscle, the separable connection permitting selective separation of the tool main body from the catheter main body in response to proximal movement of the insertion tool when the expanded balloon restrains the catheter main body against proximal movement from the use position (paragraph [0052]; Figs. 3, 4A and 4B, delivery system 40 capable of forming separable connection with stent 10); and

a separable connection including a selectively disconnectable bridging structure extending between the catheter main body and the tool main body, the bridging structure fastening together the catheter and tool main bodies when the bridging structure connected, the bridging structure releasing the tool and the catheter main bodies from one another when the bridging structure is disconnected to permit separation of the tool main body from the catheter main body in response to continued proximal movement of the insertion tool when the expanded balloon restrains the

catheter main body against proximal movement from the use position (paragraph [0047] and Fig. 3, delivery system 40 comprising connection arm 46 and opening 52 permitting connection to bulbar segment 20).

Gellman provides the advantage of securing a stent with an insertion tool during manipulation (paragraph [0047]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Rioux as discussed with the separable connection and selectively disconnectable bridging structure as taught by Gellman in order to secure a stent with an insertion tool.

25. Regarding claim 41, Rioux discloses an assembly further comprising:

an inflation tube having a distal end, a proximal end and a length extending between the distal and proximal ends, the distal end connected to the catheter main body, the length sufficient to extend from the catheter main body through the urinary canal to the exterior opening when the indwelling catheter is located in the use position, the inflation tube and the catheter main body defining an inflation passageway extending from the proximal end of the inflation tube to the balloon through which to deliver inflation fluid for expanding the balloon (column 7, lines 42-47 and Fig. 3, tube 3 connected to inflatable balloon 1).

Double Patenting

26. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

27. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 16 and 17 of copending Application No. 10/921,356 to Bolmsjo et al. (US Patent Application Publication No. 2005/0080399) herein "Bolmsjo '399." Although the conflicting claims are not identical, they are not patentably distinct from each other because:

28. Regarding claim 1, Bolmsjo '399 discloses an indwelling catheter to drain urine from a bladder to a location adjacent to a urinary sphincter muscle in a urinary tract which also includes a urinary canal extending from the sphincter muscle to an exterior opening, comprising:

a main body having a distal end, a proximal end and a length sufficient to position the distal end within the bladder and to position the proximal end adjacent to and distal of the sphincter muscle within the urinary tract, the main body defining an urine drainage interior passageway extending from the distal end to the proximal end (Bolmsjo '399 claim 1);

a balloon attached to the distal end of the main body, the balloon expandable in size within the bladder to maintain the distal end in the bladder and restrain the main body against proximal movement within the urinary tract from a use position, the use position locating the distal end of the main body in the bladder and the proximal end of the main body adjacent to and distal of the sphincter muscle (Bolmsjo '399 claims 1 and 16, distal anchor comprising a balloon);

an inflation tube having a distal end, a proximal end and a length extending between the distal end proximal ends, the distal end connected to the main body, the length sufficient to extend from the main body through the urinary canal to the exterior opening when the main body is in the use position, the inflation tube and the main body defining an inflation passageway extending from the proximal end of the inflation tube to the balloon through which to deliver inflation fluid for expanding the balloon (Bolmsjo '399 claim 16); and

a coiled section of the inflation tube formed at a position along the inflation tube to locate the coiled section within the urinary canal adjacent to and proximal of the sphincter muscle when the main body is located in the use position, the coiled section interacting with a constriction of the urinary tract by the sphincter muscle to restrain the main body against distal movement within the urinary tract from the use position (Bolmsjo '399 claim 17).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

29. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25, 28, 40 and 41 of copending Application No. 11/246,801 Bolmsjo et al. (US Patent Application Publication No. 2006/0111691) herein "Bolmsjo '691." Although the conflicting claims are not identical, they are not patentably distinct from each other because:

30. Regarding claim 1, Bolmsjo '691 discloses an indwelling catheter to drain urine from a bladder to a location adjacent to a urinary sphincter muscle in a urinary tract which also includes a urinary canal extending from the sphincter muscle to an exterior opening, comprising:

a main body having a distal end, a proximal end and a length sufficient to position the distal end within the bladder and to position the proximal end adjacent to and distal of the sphincter muscle within the urinary tract, the main body defining an urine drainage interior passageway extending from the distal end to the proximal end (Bolmsjo '691 claim 25);

a balloon attached to the distal end of the main body, the balloon expandable in size within the bladder to maintain the distal end in the bladder and restrain the main body against proximal movement within the urinary tract from a use position, the use position locating the distal end of the main body in the bladder and the proximal end of the main body adjacent to and distal of the sphincter muscle (Bolmsjo '691 claims 25 and 28, distal anchor comprising a balloon);

an inflation tube having a distal end, a proximal end and a length extending between the distal end proximal ends, the distal end connected to the main body, the

length sufficient to extend from the main body through the urinary canal to the exterior opening when the main body is in the use position, the inflation tube and the main body defining an inflation passageway extending from the proximal end of the inflation tube to the balloon through which to deliver inflation fluid for expanding the balloon (Bolmsjo '691 claim 40); and

a coiled section of the inflation tube formed at a position along the inflation tube to locate the coiled section within the urinary canal adjacent to and proximal of the sphincter muscle when the main body is located in the use position, the coiled section interacting with a constriction of the urinary tract by the sphincter muscle to restrain the main body against distal movement within the urinary tract from the use position (Bolmsjo '691 claim 41, proximal anchor section comprising a coiled section).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

31. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Rioux et al. (US Patent 6,494,855)
- Torchio (US Patent 5,514,178)
- Freyman (US Patent 6,945,957)
- Boussignac (US Patent Application Publication No. 2002/0111582)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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